8EHQ-0694-13062s

CMA CHEMICAL MANUFACTURERS ASSOCIATION

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VIA HAND DELIVERY
June 8, 1994

8EHQ-94-13062
88940000304

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Attention: Section 8(e) Coordinator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: TSCA Section 8(e) Reporting/Notification for Methyl Bromide

Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) hereby submits for your office's information, notice of a report regarding methyl bromide (CAS No. 74-83-9) that has been submitted to EPA pursuant to Section 6(a)(2) of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). This notification is made on behalf of the members of the Methyl Bromide Industry Panel. The Panel consists of Albemarle Corporation (formerly part of Ethyl Corporation), Ameribrom, Inc., Great Lakes Chemical Corporation and TriCal, Inc.

The reported information stems from preliminary toxicity testing in dogs being conducted pursuant to California's Birth Defect Prevention Act of 1984 (SB950). Specifically, the MBIP is conducting the study establish dose levels for a Chronic Dog Inhalation Study which is required for the continued registration of methyl bromide as a pesticide in California.

Based upon the explicit exemption for pesticides contained in Section 3 of the Toxic Substances Control Act (TSCA), and EPA's TSCA 8(e) Statement of Interpretation and Enforcement Policy, the Panel believes that the comparative toxicity study is not subject to TSCA Section 8(e) reporting requirements, expecially because the testing was conducted at EPA's request with regard to the specific pesticide uses of the chemical substance.

The Panel sought confirmation of this understanding from EPA officials in both the Office of Pesticide Programs and the Office of Pollution Prevention and Toxics, but received conflicting opinions regarding the application of TSCA to chemicals regulated under FIFRA. In light of the lack of a consistent policy on the applicability of TSCA to chemicals also regulated under FIFRA, the Panel is notifying the TSCA 8(e) Coordinator of the attached submission to the Office of Pesticide Programs as a precaution.

RECEIVED 6/20/94

2501 M Street, NW, Washington, DC 20037 Telephone 202-887-1100 Fax 202-887-1237

Responsible Care® A Public Commitment

The filing of this notice does not authorize any use of the information by any person outside the EPA Office of Pesticide Programs or any other release of the reported information to the public. The studies are the property of the Methyl Bromide Industry Panel and its members and, as such, must be protected by the Agency from public disclosure.

If you have any questions regarding this notice, please call me at 202/887-1293.

Sincerely,

Kathryn A. Rosica

Kathryn A. Rosica
Manager
Methyl Bromide Industry Panel

Attachment

cc: Methyl Bromide Industry Panel

CHEMICAL MANUFACTURERS ASSOCIATION

VIA CERTIFIED MAIL
June 8, 1994

FIFRA Section 6(a)(2)
Document Processing Desk
Office of Pesticide Programs - H7504C
U.S. Environmental Protection Agency
401 M Street, NW
Washington, DC 20460-0001
ATTN: Barry O'Keefe

Re: FIFRA Section 6(a)(2) Report

Dear Mr. O'Keefe:

On behalf of the Methyl Bromide Industry Panel (MBIP), the Chemical Manufacturers Association submits the attached information pursuant to Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the EPA guidance on Section 6(a)(2) reporting requirements published in the Federal Register on July 12, 1979 (1979 Guidance)[1]. The MBIP consists of three manufacturers of technical product -- Albemarle Corporation (formerly part of Ethyl Corporation), Ameribrom, Inc. and Great Lakes Chemical Corporation -- and one major formulator, TriCal, Inc.

Pursuant to the data requirements of California's Birth Defects Prevention Act of 1984 (SB950), the MBIP is jointly conducting a Chronic 1-Year Dog Inhalation Study. As part of the preliminary work being done to conduct the definitive study, a 28-day study was designed to establish appropriate dose levels. As more fully explained in the attached summary, the 28-day study was extended for two weeks at a higher dose level for one group of test animals. This extended portion of the study ended on June 3, 1994.

According to the 1979 Guidance, the Agency does not require the routine submission of information regarding preliminary and incomplete testing results. Rather, registrants have time after testing has been done to complete the final analysis of study results[2]. Nonetheless, some of the specific effects shown at the highest dose level may not be known by the Agency. Thus, as a precaution, the MBIP is advising EPA of the attached information.

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[1] 44 Fed. Reg. 40716 (July 12, 1979).

[2] See 44 Fed. Reg. 40716, 40718.

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Summary of Effects Shown

A 28-day, repeated exposure inhalation toxicity study in beagle dogs with methyl bromide was initiated at Pharmaco:LSR on April 18, 1994. Six groups of eight dogs (4 males and 4 females) were exposed to test concentration of or ppm. The dogs were exposed 7 hours per day, five days per week (Monday through Friday). All dogs from the , and ppm concentrations as well as 2 males and 2 females from the control group were sacrificed after 23 exposure days. An additional two weeks of exposure was planned for the ppm dogs at a methyl bromide concentration of ppm. Exposure for the remaining control dogs and for the ppm dogs was extended for the additional two week interval, as well. A veterinary neurologist evaluated all dogs on the day following the 20th exposure.

No significant clinical signs of toxicity were seen during or after exposure for the animals from the or ppm groups. Evaluation by the veterinary neurologist revealed no treatment related findings at any exposure concentration.

Exposure of the ppm dogs at a ppm concentration started on Friday, May 20, followed by two days of nonexposure and the 5 consecutive daily exposures started on Monday, May 23. Clinical signs through Wednesday, May 25 (four exposures) were limited to Approximately 2 hours after the 5th exposure, clinical signs such as i and were noted in 6 dogs (4 males, 2 females). Prior to exposure on Friday, May 27, one dog showed while other dogs appeared normal. After the 7 hour exposure, seven dogs showed that included y and . Approximately 18 hours after this exposure, 3 male dogs were , and sacrificed. The veterinary neurologist evaluated the remaining 5 dogs at approximately 21 hours post exposure and noted in all animals. was noted for the remaining 5 dogs through sacrifice at approximately 84 hours after the last exposure. The and ppm animals showed no effect throughout the extended duration period.

If you have any questions concerning this report, please call me at (202) 887-1293.

Sincerely,

Kathryn A. Rosica
Manager
Methyl Bromide Industry Panel

Attachment

cc: Methyl Bromide Industry Panel

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Kathryn A. Rosica
Manager, Methyl Bromide Panel
Chemical Manufacturers Association
2501 M Street, N.W.
Washington, D.C. 20037

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 04 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13062 A

Triage of 8(e) Submissions

Date sent to triage: 12/16/96

NON-CAP CAP

Submission number: 13862A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

~~THIS SUBMISSION REQUIRES CBI TRIAGE; FILE IN CBI TRIAGE FOLDER~~

For Contractor Use Only

entire document: ~~0~~ 1 2 **pages** 1,2 **pages** 1,2,5

Notes:

Contractor reviewer : POR **Date:** 9/23/94

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Subm ssion # 8EHQ-0694 -13062 (5) SEQ. A

TYPE (INT.) SUPP FLWP

SUBMITTER NAME: Chemical Manufacturers Association

SUB. DATE: 06/08/94 OTS DATE: 06/09/94 CSRAD DATE: 06/20/94

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:

CAS#
74-83-9

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCC/REL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQEST DELAY	01 02 04	(0248)	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	01 02 04	0224	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
0212	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
(0213)	SUB ACUTE TOX (ANIMAL)	(01) 02 04	0228	ALLERG (ANIMAL)	01 02 04			
(0214)	SUB CHRONIC TOX (ANIMAL)	(01) 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
(0215)	CHRONIC TOX (ANIMAL)	(01) 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA:

NON-CBI INVENTORY
(YES (CONTINUE))
NO (DROP)
DETERMINE

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER:

SPECIES
DOG

TOXICOLOGICAL CONCERN:
LOW
MED ND
HIGH

USE: Pesticide

PRODUCTION:

COMMENTS: Non-Cap

Reviewed
(No information)

"13062A"="ND?="SUBACUTE TOXICITY IN BEAGLE DOGS IS OF UNDETERMINED CONCERN. DOGS (4/SEX/DOSE) WERE EXPOSED BY INHALATION TO UNSTATED DOSES OF PHARMACO:LSR 7 HOURS/DAY, 5 DAYS/WEEK, FOR 28 DAYS. ALL DOGS FROM CERTAIN EXPOSURE GROUPS AND 4 CONTROLS WERE SACRIFICED AFTER 23 DAYS. NO CLINICAL SIGNS OF TOXICITY WERE SEEN DURING OR AFTER EXPOSURE IN CERTAIN GROUPS. DOGS IN ONE GROUP WERE EXPOSED TO AN ALTERED CONCENTRATION OF THE TEST SUBSTANCE FOR AN ADDITIONAL 2 WEEKS; EXPOSURE FOR THE REMAINING CONTROL DOGS AND DOGS IN A CERTAIN GROUP WAS EXTENDED FOR 2 WEEKS AS WELL. CLINICAL SIGNS (UNSTATED) WERE OBSERVED IN 4/4 MALES AND 2/4 FEMALES AFTER THE 5TH EXPOSURE. APPROXIMATELY 18 HOURS AFTER THE 7TH EXPOSURE, 3 MALES WERE SACRIFICED. SYMPTOMS WERE NOTED IN THE REMAINING 5 DOGS AT 21 HOURS POST-DOSING AND THESE WERE SACRIFICED AT 84 HOURS POST-DOSING. 2 GROUPS SHOWED NO EFFECT THROUGHOUT THE EXTENDED DURATION PERIOD. DOSES AND SYMPTOMS WERE NOT STATED."